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Design and Manufacturing method of Prosthetic Socket without physical presence of the Amputee

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Abstract

Background and aim: Traditional and advanced development methods of prosthetic sockets for limb amputations has been well investigated in the literature but some issues still remain with these procedures: previous experience of the prosthetist, large amount of waste material and hardware and software costs. The aim of the technical note was to propose a low-cost method for digitizing the residual limb and generate its corresponded prosthetic socket; and where the physical presence of the amputee is not a requirement.

Technique: Three photographs are required as input to generate 2D profiles of the contour of the residual limb, which define its geometric shape, a 3D model is generated using standard CAD operations; and then, the prosthetic socket is generated using a sculpting software.

Discussion: Experimental tests validated the prosthetic socket fit in a real case application; the generated prosthetic socket was comparable with the prosthetic socket currently used by the patient.

The proposed method presents a virtual prosthetic socket design procedure that use open-source software and CNC low-cost hardware that facilitates its manufacturing; it also opens the possibility to generate prosthetic socket remotely.

Keywords: Prosthetic socket, Computer-aided design, residual limb digitizing, 3D reconstruction

Background and aim

The development of prosthetic sockets for lower and upper limb amputations has been well researched in the literature [1–6]; the prosthetist profession focuses on the development of this element. However, some issues arise with traditional procedure: the fabrication precision depends on the previous experience of the prosthetist, large amount of waste material generated and the machinery cost. Modern computerized method tries to fix this issues [7,8], however, those method require expensive hardware and software. A totally different solution and approach consists of adapting an insert directly to the bone of the residual limb, a medical procedure named Osseointegration; an adapter serves as a connector for fitting a prosthetic knee. It offers several advantages, although it is still in the expansion phase since few doctors perform it and few institutions have standardized it [9–11]. Table 1 resumes advantages and limitations of prosthetic socket fabrication method and Osseointegration.

Applications of 3D reconstruction from photographs has been investigated in the past [12,13] for human representation. Based on those approaches, this article presents a virtual method for design and manufacture prosthetic socket, the absence of physical presence of the amputee is the main advantage of the proposed method. In this article, we describe the technique, the open-source tools implemented and describe a real transtibial case application and compare the method with other socket manufacturing processes.

Table 1. Comparison of solutions employed as residual limb and prosthesis connector

Method	Advantages	Limitations
Traditional socket fabrication method	Widely studied and implemented over years Reliable solutions Lower cost than advanced method	*Previous experience strongly influences the result* *Generate a lot of waste material* *Difficult to replicate if needed*
Advanced socket fabrication method	*Greater precision than traditional method* *Reduces material waste* *Shorter manufacturing times*	*Requires particular training and learning* *Not common in prosthetic Industry* *Requires computer equipment and proprietary software*
Osseointegration (OI)	*Eliminates discomfort/problems caused by the socket* *More comfortable to sit* *Does not produce perspiration* *Ideal for small residual limbs*	*Implicit risk in the performed surgeries* *Risk of infection* *Implementation requires 12-18 months*

	Fewer visits to the prosthetist	*High cost of surgeries* *Not suitable for growing children or over 70 years old amputees* *Not suitable for high impact activities*

Technique

The proposed methodology is based on the use of three photographs and low-cost tools to obtain the virtual model of the residual limb and a CAD model of the prosthetic socket. Figure 1, outline the proposed technique, the procedure, tasks to perform to obtain a residual limb CAD model and the socket fabrication stage is presented. With this procedure, the use of plaster casts or expensive scanner is eliminated, and could be carried out without the physical presence of the user.

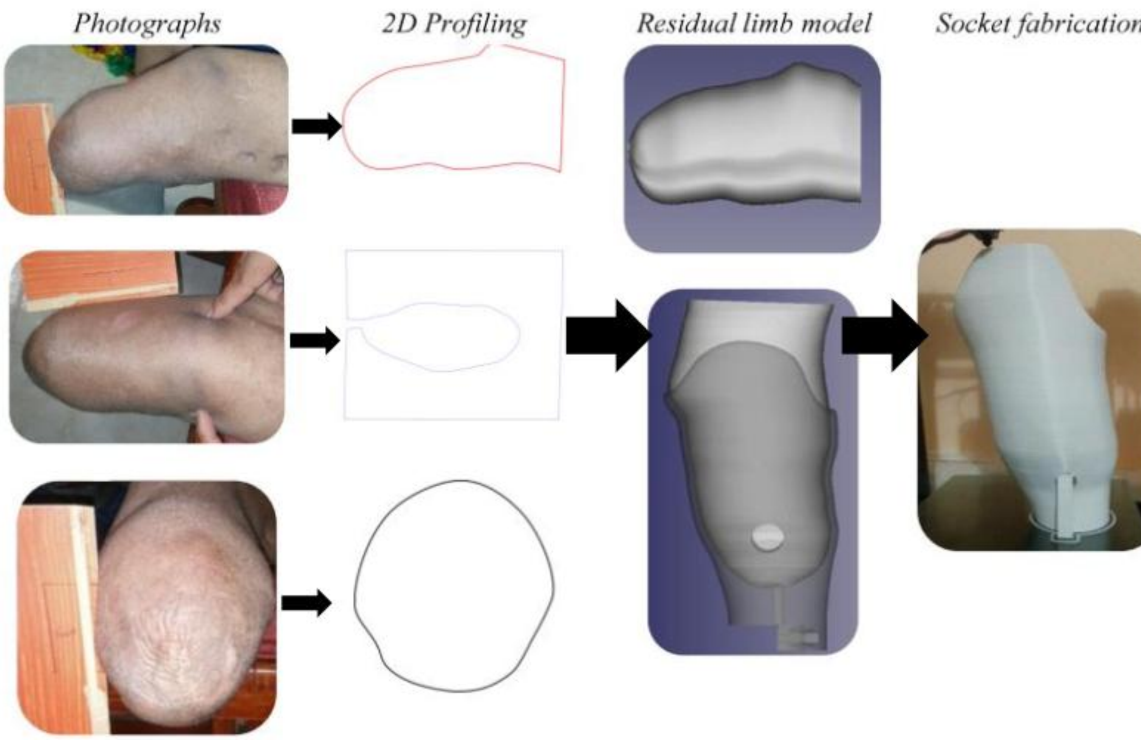

Figure 1. General proposed method procedure

Contour generation
Three photographs of the residual limb, obtained from the lateral, superior and axial views, are required to derive the geometric model of the residual limb. A measurement reference in the image, such as a rule or an item of known size, is needed to adjust the size of the image respect to the real dimension. Bezier curves tool is used to draw the profiles of the residual limb. For this task, the open-source software Inkscape was selected.

Scaling images
Each generated contour must be scaled to the actual size of the residual limb. The adjustment is made with the following formula:

Reduction/Augmentation [%] = Real measurement/Virtual measurement x 100

Use same units (millimeters and millimeters for example)

Residual limb CAD generation
The lateral and superior profiles are used to create reference of the residual limb solids and then, with the axial profile and the restrictions of the superior and lateral profiles, a series of cloned sketches are created, separated by a distance of 3-5mm (Figure 2), to generate the model of the residual limb. Loft tool creates the residual limb solid. For this task, the open-source software FreeCAD was selected.

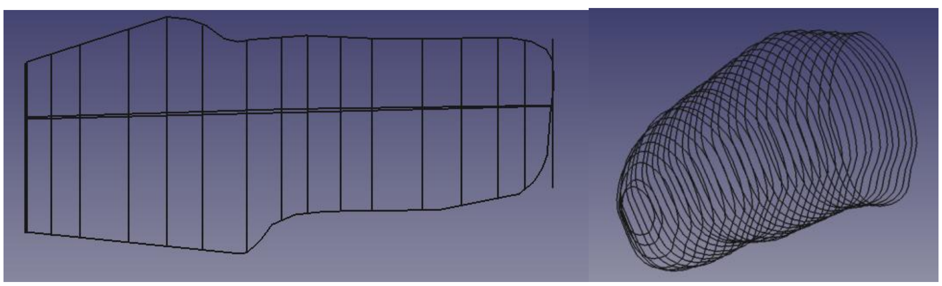

Figure 2. Residual limb axial profile clones restricted by lateral and superior profile.

Circumference profile reductions
To guarantee adjustment and maintain a good fixation with the fabricated socket, the Gabbiadini's recommendations[7] are used on the reduction of 1% in the base of the limb and 2% in the upper part.

3D model of the socket
Using the generated model of the residual limb, and a surface modifier (sculpting) software, one can create the prosthetic socket for the corresponding residual limb. The software procedure includes:
Smooth the residual limb model,
Select the curvature of the prosthetic socket (according to user’s prescription)6,
Offset the surface shape adding thickness to the part,
And, connect it to a base that will then accommodate a standard adapter for the rest of the prosthesis.
For this task, we used Meshmixer software; an open-source option is Blender.

Manufacturing
3D printing technology is used to generate the prosthetic socket for the patient. Filament Fused Fabrication (FFF) is a low-cost reliable option. It is important to fabricate the part

with a suitable height of layer that that produces a smoothed inner surface without sharp edges that cause discomfort to the user.

The implemented parameters for additive manufacturing are:
Material used: ABS. Other alternatives are PolyEthylen Glycol Terephthalate (PETG) and Polycarbonate (PC)
Printing speed: 60mm/s in the infill
Printing temperature: 240ºC
Extruder nozzle: 0.5mm
Layer height: 0.30mm
Infill: 70%

Results

The proposed technique has been applied in a real case of application with the help of a 33-year-old male with transtibial amputation (80kg weight and 1.80m of height). We performed experimental tests to validate the prosthetic socket fit; Figure 3 presents the amputee using the developed transtibial socket.

The participation of the patient was voluntary and an informed consent was obtained from him before his participation in this study. The Ethics Committee of the Universidad del Norte (Barranquilla, Colombia) approved this study.

Figure 3. Transtibial socket generated with the proposed method.

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Discussion

Table 2 compares different factors of three main methodologies for design and manufacture prosthetic sockets.

Table 2. Comparison of prosthetic socket development methodologies

	Method		
Factor/characteristic	Traditional	Advanced	Proposed
Required Machinery/Hardware	Cast, Plaster, tape measure, Industrial oven, Compressor	High precision 3D scanner, PC, CNC machining center	Digital camera(smartphon), PC, 3D printer
Expertise required	High	High	Low
Design and manufacturing time* (hours)	Design: 2 Manufacturing: 15	Design: 3 Manufacturing: 8	Design: 5 Manufacturing: 5
Precision	High	High	- **
Type of Software(s)	None	Proprietary	Open-source and free
Type of work of the prosthetist/designer	Physical	Virtual-Physical	Virtual
Possibility of remote work	No	No	Yes
Cost	Medium	High	Low

* Estimated according to observed values. It varies according to the experience of the prosthetits.

**More data needed to define the precision. Preliminary results show viability.

This methodology exhibit advantages over other methodologies, highlighting: the basic required equipment (hardware), the null cost in software and the possibility of working remotely. More clinical trials with more amputees are needed to determine the accuracy of the method.The generated prosthetic socket was compared with the prosthetic socket currently used by the patient; the general shape is very similar (Figure 4). The 3D printed socket was smaller since the photographs were taken without the liner he currently uses (see Figure 1).

Figure 4. Different views of user's current prosthetic socket (left) and fabricated (right).

In terms of manufacturing, the design process with computerized tools facilitates the manufacturing process and increase precision because it implement computerized numerical control (CNC) equipment (3D printer) and reduces waste material generated by the traditional manufacturing method.

Currently, some orthopedic centers utilize computerized tools to create prosthetic sockets, we compare established software with the proposed technique and the software it incorporate.

Rodin4D, Canfit™ and similar:
Advantages: Company support, Developed by experienced prosthetists
Disadvantages: Cost, Proprietary software, For Windows only
Proposed method:
Advantages: Cost, Open-source, Available for Windows, Mac and Linux
Disadvantages: Require more clinical validation

Key points

A computerized method to produce prosthetic sockets that uses open-source tools to design and low-cost equipment (additive manufacturing by fused filament) to manufacture it.

The virtual method offer a novel procedure to manufacture without amputee physical presence in the orthopedic laboratory, the patient could send the require photographs and the socket production can be done remotely, allowing to reach people located in regions of difficult access.

This computerized process generates lesser waste than manual manufacturing process and can maintain a historical (virtual) record of the residual limb and devices the person has used throughout his life.

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